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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,805	12/01/2003	Mark Edward Bunnage	PC10384B	5555
28523	7590	09/13/2004	EXAMINER	
			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,805	BUNNAGE ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 January 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-24 and 26-30 is/are rejected.
- 7) Claim(s) 25 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an application filed on 12/1/03. There are thirteen claims pending and thirteen under consideration. Claims 24-27 are compound claims. Claims 18-23 and 28-30 are method of making claims. This is the first action on the merits. The application concerns some intermediate compound and processes of making compounds related to Sildenafil.

Election/Restrictions

2. The present claims correspond to Groups II-XIV of parent application 09/886,643. Although the present claims are patentably distinct, as a courtesy to the Applicants, all pending claims will be searched and examined.

Priority

3. The status of non-provisional parent application should also be included. Since the parent application has become a patent, please update the first line of the specification with the expression "now Patent No. 6,730,786" following the filing date of the parent application.

Claim Objections

4. Claim 22 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because reference to two sets of claims to different features is not permitted. See MPEP § 608.01(n). The Examiner suggests adding the structure of radical R^a.

5. Claim 24 is objected to because of the following informalities: It is a compound claim, yet it depends upon a method claim. Appropriate correction is required. The Examiner suggests adding the structure of compound II.

6. Claim 25 is objected to because of the following informalities: It is a compound claim, yet it depends upon a method claim. Appropriate correction is required. The Examiner suggests adding the structure of compound III.

7. Claim 26 is objected to because of the following informalities: It is a compound claim, yet it depends upon a method claim. Appropriate correction is required. The Examiner suggests adding the structure of compound VI.

8. Claim 27 is objected to because of the following informalities: It is a compound claim, yet it depends upon a method claim. Appropriate correction is required. The Examiner suggests adding the structure of compound VIIA.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 19, 24, 26, and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Throughout these claims, Applicants use the term “general formula”. This is indefinite because

it implies more than one formula is claimed. The Examiner suggests deleting the word "general".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-23 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for said dehydrogenation being carried out in the presence of a dehydrogenation agent selected from: palladium on carbon, palladium on carbon in the presence of a hydrogen acceptor and/or an acid, a high oxidation potential quinone, oxygen, MnO₂, or triphenylmethanol in trifluoroacetic acid, does not reasonably provide enablement for all dehydrogenations. The specification does not enable any skilled process chemist or pilot-plant operator to make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims",

In re Rainer, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

a) Determining if any particular substrate would react under Applicants conditions would require synthesis of the substrate II and subjecting it to dehydrogenation with a an unknown list of oxidants, a large quantity of experimentation. b) The direction concerning dehydrogenating compound II is found in line 20, page 4, and line 5, page 6, and line 20, page 7, which merely states Applicants intent to do so. The passage spanning line 5, page 12 to line 6, page 13 gives examples of intended reagents. c) There are two working example of dehydrogenating compound II. These are found lines 24-26, page 23 and lines 15-18, page 25. Both working examples involve the solid catalyst Pd/C. d) The nature of the invention is chemical synthesis, which involves chemical reactions. e) The state of the art is no list of reagents or reaction condition exists which teach every possible "dehydrogenation reaction". Such reactions and reagents will be limited by the chemical nature of the side chains embraced by radicals R¹-R⁴, as well as the oxidatively sensitive nitrogen atoms present in the mandatory piperazine and pyrazole rings in formula II. f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. He

would know how to employ the reagents listed in passage spanning line 5, page 12 to line 6, page 13, but be unaware of how to devise additional ones.

g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. In addition, catalytic reaction, as exemplified by Applicants working examples, are inherently understood to be unpredictable, *MOBIL OIL CORPORATION v. W.R. GRACE & COMPANY*, 180 USPQ 418, *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 164, 116 USPQ 484, 490 (4th Cir. 1958), *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 368-369 (1928), *Application of Grant*, 304 F.2d 676, 679, 134 USPQ 248, 250-251 (CCPA 1962); *Rich Products Corp. v. Mitchell Foods, Inc.*, 357 F.2d 176, 181, 148 USPQ 522, 525-526 (2d Cir. 1966), cert. denied 385 U.S. 821, 151 USPQ 757 (1966); *Ling-Temco-Vought, Inc. v. Kollsman Instrument Corp.*, 372 F.2d 263, 268, 152 USPQ 446, 450-451 (2d Cir. 1967); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 132-133, 118 USPQ 122, 128-129.

h) The breadth of the claims includes all of the thousands of compounds of formula II as well as the presently unknown list of reactions embraced by the term "dehydrogenation reaction". Thus, the claims are broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

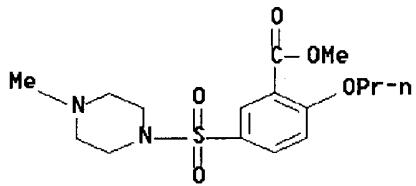
Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by Macor ('368). The compound shown below fits formula VIIIA with R^a = CH₃, R³ = propyl, and R⁴ = methyl. It is found in lines 45-67, column 36 of the reference. The ethyl homologue is found in lines 11-44, column 36.



Allowable Subject Matter

12. Claims 24 and 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

14. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


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